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REMARKS

This application pertains to novel cosmetic and dermatological preparations for the prophylaxis and treatment of rosacea.

Claims 1-16 are pending, Claim 17 being canceled by this amendment.

Claims 1, 2, 4-8 and 11-15 stand rejected under 35 U.S.C. 112, first paragraph. The Examiner views the specification non-enabling for prophylaxis of rosacea

> "due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition".

The foregoing, however, is not a reason for rejecting a claim or claims as non-enabled. The present application does not pertain to the diagnosis, it pertains to treatment and prophylaxis. Who the treatment should be applied to is a determination that can be made, e.g., by a patient's physician. Similarly, that same physician would monitor the progress of a patient under treatment.

The claimed method, however, is fully enabled by the specification. Thus, once a physician determines that his patient is in need of treatment for rosacea, or determines that

his patient should be treated for the prevention of said disease, the instant specification will enable him to perform such prophylaxis or treatment according to the invention.

The rejection of clams 1, 2, 4-8 and 11-15 under 35 U.S.C. 112, first paragraph, should accordingly now be withdrawn.

Claims 1-17 stand rejected under 35 U.S.C. 112, first paragraph, because the Examiner sees the specification as enabling for only those specific NO-synthase inhibitors that are listed on pages 2-5 of the specification.

Applicants teach a method for the prophylaxis and treatment of rosacea which comprises applying a compound selected from the group consisting of NO-synthase inhibitors and derivatives thereof. Throughout the specification, Applicants refer to NO-synthase inhibitors as a group; and give some specific examples. These examples are non-limiting, however, and there is nothing in the specification that would cause any person having skilled in the art to believe that the invention was limited to only the specifically-listed NO-synthase inhibitors. More to the point, any person skilled in the art reading Applicants' specification would be enabled to use NO-synthase inhibitors in the method by simply using them in the way taught by the specification. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation (MPEP §2164.01). A person skilled in the art who wished to use an NO-synthase inhibitor that does not happen to be listed among the preferred compounds given

in the specification would use such NO-synthase inhibitor in the same way that Applicants teach they should be used. What is it that the Examiner thinks such a person would not be able to do?

The fact is that there is no non-enablement issue here, and the rejection of claims 1-17 under 35 U.S.C. 112, first paragraph, should now be withdrawn.

Claim 1 and those dependent thereon stand rejected under 35 U.S.C. 112, second paragraph, for use of the phrase "an effective amount". This phrase is in common use in this art, and is well understood to require that the recited compound be used in an amount sufficient to be effective for the recited use. There is nothing indefinite about such language, and every person skilled in this art will understand what it means. It is respectfully pointed out that the very reference the Examiner himself cites in the present case, Breton, uses the same phrase...see claim 1 of the Breton reference.

The rejection of claim 1 and those dependent thereon under 35 U.S.C. 112, second paragraph, should accordingly now be withdrawn.

Turning now to the art rejections, claims 1-16 stand rejected under 35 U.S.C. 102(e) as anticipated by either Breton et al. (U.S. 5,795,574) or Ptchelintsev et al (US 5,847,003).

Breton, however, concerns the treatment of disorders associated with an excess in the synthesis or release of substance P, using extracts from non-photosyntheic

filamentous bacterium which is a substance P antagonist, in a cosmetically or pharmaceutically acceptable carrier. The compositions used could, in addition to the extracts from non-photosyntheic filamentous bacterium, include any of a wide variety of other substances as well, including NO-synthase inhibitors. Such NO-synthase inhibitors are used for their effect as mediators of inflamation (col. 8, lines 54-61).

Notably, however, there is no teaching or suggestion about the treatment or prophylaxis of rosacea, no teaching or suggestion of the use of the NO-synthase inhibitors in the absence of the extracts from non-photosyntheic filamentous bacterium, and no discussion of the effect that the extracts from non-photosyntheic filamentous bacterium have on a patient suffering from rosacea.

While the Examiner would like to say that Applicants' method is "inherent" in the teachings of Breton, there is no evidence of record that it is. The effect of the extracts from non-photosyntheic filamentous bacterium, which must be present in Breton's compositions, on rosacea, are not known from Breton, and it is not known from Breton how the presence of the extracts from non-photosyntheic filamentous bacterium in the compositions would affect Applicants' method of treatment or prophylaxis. Thus, it cannot fairly be said that Applicants' method is "inherent" in Breton's. No person skilled in the art reading Breton would be led to the treatment or prophylaxis of rosacea using NO-synthase inhibitors.

The Ptchelintsev disclosure, on the other hand, concerns the use of certain oxa compounds for the treatment of "the signs of dermatological aging". The oxa compounds

can be used in combination with other cosmetic and pharmaceutical actives and excipients. Ptchelintsev also discloses, at col. 9, lines 40-53 that his oxa compounds can be coformulated with nitric oxide synthase inhibitors as a way of reducing skin redness, vasodilation and inflammatory reactions, ***especially in response to electromagnetic and ionizing radiation or to the action of chemically or biochemically aggressive compounds.*** Thus, the only time that Ptchelintsev would include NO-synthase inhibitors would be when the compositions were to be used for the treatment of skin redness caused bo exogenous factors, such as the sun.

Nowhere, however, does Ptchelintsev teach or disclose the use of NO-synthase inhibitors for the prophylaxis or treatment of rosacea, and no person skilled in the art would ever be led by Ptchelintsev to use NO-synthase inhibitors for the treatment of rosacea. Moreover, Ptchelintsev's compositions must always include the oxa compounds, and nothing is taught about the effect that such compounds might have on rosacea. Without knowing this, one would never apply such compositions to a patient suffering from rosacea, as one would not know whether or not the oxa compounds would be harmful to such a patient. Applicants' method is therefore not "inherent" in Ptchelintsev's teachings.

The rejection of claims 1-16 under 35 U.S.C. 102(e) as anticipated by either Breton et al. (U.S. 5,795,574) or Ptchelintsev et al (US 5,847,003) should accordingly now be withdrawn.

Claims 1-3, 7-10 and 14-17 stand rejected under 35 U.S.C. 102(b) as anticipated

by Abluwalia et al (WO 95/24884).

According to the Examiner, Abluwalia teaches a composition that contains NO synthase inhibitors, and "inherently" treats rosacea.

However, Ahluwalia is concerned with the removal of unwanted hair, and discloses absolutely nothing about rosacea. Patients suffering from rosacea but not suffering from unwanted hair would never use Ahluwalia's compositions.

There is nothing in Ahluwalia that would teach or suggest a treatment for rosacea; and nothing to teach or suggest that those who suffer from unwanted hair would, at the same time, also suffer from rosacea.

Accordingly, the treatment of rosacea is not inherent in the treatment of unwanted hair.

The rejection of claims 1-3, 7-10 and 14-17 under 35 U.S.C. 102(b) as anticipated by Abluwalia et al (WO 95/24884) should accordingly now be withdrawn.

The rejection of claim 17 under 35 U.S.C. 102(b) as anticipated by Bloy is obviated by cancellation of said claim.

Claims 1-4, 7-11 and 14-16 stand rejected under 35 U.S.C. 102(b) as anticipated

by Giacomoni (WO 96/26711)

WO 96/26711 discloses the use of NO synthase inhibitors for reducing the skin irritant effect of active agents which are used in topical applied cosmetics or pharmaceuticals. Such medical active agents are cited (page 7, line 40 - page 8, line 27).

Pharmaceutical compositions according to the invention are in particular useful in the field of special treatments and in particular appropriate for compositions containing retinoids (page 8, lines 34-37). The special treatments are disclosed in the following (page 8, item 1) - page 10, item 16)). The treatment of rosacea is disclosed in item 1) (page 8, line 41).

The composition claim 15 is directed to compositions with a content of at least one NO synthase inhibitor and at least one compound suitable to cause an irritation of the skin.

All this means that the medical active agent (retinoids) causes irritations which are reduced by the inhibitor according to the invention. NO synthase inhibitors are not disclosed to be effective in and of themselves against rosacea.

The WO '711 reference therefore neither teaches nor suggests the use of NO-synthase inhibitors for the treatment of rosacea. Nothing in this reference would enable the use of NO-synthase inhibitors for the treatment of rosacea.

The rejection of Claims 1-4, 7-11 and 14-16 under 35 U.S.C. 102(b) as anticipated by Giacomoni (WO 96/26711) should accordingly now be withdrawn.

Claims 5, 6, 12 and 13 stand rejected under 35 U.S.C. 103(a) as obvious over Giacomoni in view of either Breton or Ptchelintsev et al.

The Examiner cites Breton and Ptchelintsev as teaching sunscreen agents.

Nothing in either of these references would suggest combining a sunscreening agent with a NO-synthase inhibitor.

More important, however, is the fact that merely combining a sunscreen with Giacomoni's composition would never result in a method for the prophylaxis or treatment of rosacea by the application of an amount of NO-synthase inhibitor that would be effective for such treatment.

Accordingly, the rejection of Claims 5, 6, 12 and 13 under 35 U.S.C. 103(a) as obvious over Giacomoni in view of either Breton or Ptchelintsev should now be withdrawn.

In view of the present amendments and remarks it is believed that claims 1-18 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.